

Health Care Provider Guidance for At-Home Antigen Test Kit Results

Michigan.gov/Coronavirus

August 25, 2021

At-home antigen tests are available for the public to purchase to test for COVID-19. Currently, the U.S. Food and Drug Administration (FDA) has authorized five at-home COVID-19 testing kits under emergency use authorization. The kits are designed to use a self-administered nasal swab. This guidance document will help health care providers assist their patients with interpreting test results and when to do additional testing.

About at-home antigen tests

Antigen tests are available for purchase from several retailers in Michigan. There are five FDA-approved tests that are available for home use:

- Abbott BinaxNow
 - The Binax over-the-counter (OTC) at home kit contains two testing cards. These tests include the BinaxNow card and a nasal swab.
 - o BinaxNow is a serial process by which the individual is meant to take the first test and then confirm initial results with the second test. For accurate results, each test should be used over the course of three days, with at least 36 hours between the two tests.
- Cue Health
 - The Cue OTC test cartridge pack has a single-use, self-contained test cartridge and a swab used for minimally invasive nasal sample collection.
- Ellume
 - The Ellume test includes a sterile nasal swab, a dropper, processing fluid and a Bluetooth-connected analyzer for use with an app on a smartphone. The app gives users video instructions to perform the test and results show up in less than 15 minutes.
- Quidel QuickVue
 - The Quidel QuickVue antigen test can give results in 10 minutes using a nasal swab sample placed in a test tube followed by a test strip. Colored lines on the test strip indicate positive or negative test results.
- Lucira
 - o To self-administer the Lucira Check It test, users swirl the sample nasal swab in a vial before placing it in the test unit. It is possible to read the results from the unit's light-up display in 30 minutes or less to show a positive or negative result for SARS-CoV-2.



How to discuss at-home test results with the patient

At-home testing kits advise patients to contact their health care provider if they have questions about testing and to report the results of their tests (both positive and negative). This document provides guidance on how to advise patients on their positive, negative, as well as error, canceled or invalid results:

COVID-19 Viral Testing Tool

This interactive web-based tool is designed to help both health care providers and individuals understand COVID-19 testing options.

Positive Results:

- Report the case to the <u>local health department</u> and include patient demographics and patient contact information with that report.
- Ask the patient about their current symptoms.
 - If the patient is symptomatic:
 - Assess the severity of the patient's symptoms and counsel them about whether they should seek medical attention immediately or when they should consider seeking medical attention.
 - Recommend the patient isolate from others for 10 days after the date of symptom onset.
 - Recommend the patient stay home and avoid contact with other household members who live with them. Recommend they wear a mask that covers their mouth and nose, and practice frequent hand washing. When soap and water are not available, suggest the use of a hand sanitizer with 60% or higher of alcohol.
 - Have the patient inform anyone they had close contact with in the last few days about their positive results. Individuals identified as close contacts should enter a 10-day quarantine following the last contact with the patient.
 - The patient can stop isolating after 10 days as long as symptoms are improving and the patient has been without a fever for 24 hours without using any fever-reducing medicine, such as acetaminophen (e.g., Tylenol) or ibuprofen (e.g., Advil or Motrin). If the patient was severely ill or is immunocompromised, the patient may need to isolate for longer than 10 days, possibly up to 20 days.
 - If the patient is asymptomatic:
 - Discuss with the patient risk factors (e.g., no masking, not maintaining social distancing, or attended a large gathering) for COVID-19 exposure to determine further testing.
 - The health care provider should advise the patient to isolate from others until they receive a negative PCR test result.



- Anyone who has had close contact with someone with COVID-19 should stay home for 14 days after their last exposure to that person.
- However, anyone who has had close contact with someone with COVID-19 and who meets the following criteria does NOT need to stay home:
 - Someone who has been fully vaccinated and shows no symptoms of COVID-19. However, fully vaccinated people should get tested three to five days after their exposure, even they don't have symptoms and wear a mask indoors in public for 14 days following exposure or until their test result is negative, or
 - Someone who has COVID-19 illness within the previous three months and has recovered and remains without COVID-19 symptoms.
- Additional considerations:
 - In areas of substantial and high transmission, fully vaccinated persons should get tested three to five days after exposure to someone with suspected or confirmed COVID-19, and wear a mask in public indoor settings for 14 days after exposure or until they receive a negative test result.
 - Recommend the patient tell their close contacts that they may have been exposed to COVID-19. An infected person can spread COVID-19 starting 48 hours (or two days) before the person has any symptoms or tests positive.
 - If the patient has any <u>risk factors</u> or starts to develop more severe illness, they should be instructed to seek medical care. There are treatments that the patient <u>may</u> qualify for that could reduce the risk of severe illness. More outpatients are being treated now with <u>monoclonal antibody treatments</u> authorized for patients at risk of being hospitalized.

Negative Results:

- If the patient is symptomatic with a known contact to a positive COVID-19 case, recommend the patient isolate for 10 days after the date of their symptom onset.
 - PCR testing for detection of COVID-19 for discontinuing isolation may be considered for persons who are severely immunocompromised, in consultation with infectious disease experts.
 - For all others who are not severely ill or severely immunocompromised, a testbased strategy is not recommended, and isolation and precautions should be maintained for at least 10 days.
- If the patient is asymptomatic, recommend they perform another test in 24 36 hours
 - If a subsequent test comes back positive, the health care provider should recommend the patient isolate for the full 10 days after the positive test result and notify their close contacts.
 - Recommend the patient stay home and avoid contact with other household members who live with them. Recommend they wear a mask that covers their mouth and nose and practice frequent hand washing. When soap and water are not available, use a hand sanitizer with 60% or higher of alcohol.



Error, Canceled or Invalid Results:

- Ask the patient about how they administered their test.
 - Counsel on the appropriate methods if it appears the test was not done correctly;
 encourage them to repeat the test with the correct procedure.
 - Or suggest the patient try a different at-home test or get tested at another site.
 Testing sites can be located through the MDHHS COVID-19 Testing Website.
- If they are symptomatic:
 - Recommend the patient go to a <u>testing site for another COVID test</u> and obtain a PCR test.
 - Recommend the patient stay home and avoid contact with other household members who live with them. Recommend they wear a mask that covers their mouth and nose and practice frequent hand washing. When soap and water are not available, use a hand sanitizer with 60% or higher of alcohol.
 - Counsel them about communicating with the testing facility where they are going for a PCR test that they are symptomatic and were unable to complete an at-home test.

How to report test results

Negative test results for at-home antigen tests do not need to be reported to MDHHS. However, if the health care provider administers confirmatory testing, these results must be reported.

For more information

- MDHHS Antigen Test FAQ
- Centers for Disease Control Self-Testing Guidance

